



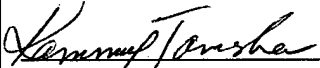
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

APPELLANT: Pierre Messier **GROUP ART UNIT:** 3771
SERIAL NO.: 10/528,006 **CONFIRMATION NO.:** 9028
FILING DATE: January 5, 2006 **EXAMINER:** Dixon, Annette
Fredricka
TITLE: FACEMASK WITH FILTERING CLOSURE

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Kammy Tamashar

October 27, 2009
Date

APPEAL BRIEF

This Appeal Brief is submitted in accordance with 37 C.F.R. § 41.37 in furtherance of the Notice of Appeal filed August 4, 2009, in support of the appeal from the final rejection of claims 1 through 9, 11 through 16 and 18 through 27 in the above-identified application.

The fee set forth in § 41.20(b)(2) of \$270.00 accompanies this Appeal Brief, along with a fee of \$65.00 associated with a Petition for Extension of Time of one month submitted herewith. Appellants believe that no other fees are due. However, the Commissioner is hereby authorized to charge any additional fees that may be due, for further extensions of time or any other purpose associated with this submission, or credit any overpayment, to Appellants' undersigned counsel's Deposit Account Number 06-0923 with reference to docket number 102785-337-NP2.

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REAL PARTY OF INTEREST

The real party of interest is Triosyn Holding, Inc, the assignee, pursuant to an assignment recorded in the records of the U.S. Patent and Trademark Office on 06/14/2005, at 06/14/2005 at Reel: 061333 beginning at Frame 0858. The beneficial owner is SafeLife, Inc.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences pending in the above-identified application that will directly affect or that will be directly affected by the Board's decision in the present appeal.

STATUS OF CLAIMS

Claims 1-9, 11-16 and 18-29 are pending in this application. Claims 10 and 17 have previously been cancelled without prejudice or disclaimer. Claims 28-29 are now being cancelled because they appear to be duplicative. Claims 1-9, 11-16 and 18-27 are rejected and are currently under appeal.

STATUS OF AMENDMENTS

Applicant filed an Amendment Under 37 C.F.R. § 1.116 on April 13, 2009 which was not entered by the Examiner.

SUMMARY OF CLAIMED SUBJECT MATTER

The following is a concise explanation of the subject matter of each of the independent claims, referring to the specification by page and line number for support.

- Claim 1 relates a facemask having a periphery adapted to abut a user's face; and a compressible gasket formed of a breathable filtering material on said periphery of the facemask. The breathable filtering material sits between the periphery of the facemask and a face of a user filling any space that may exist there between. The breathable filtering material provides an air path there through. The facemask has an area for filtering air which is interior to the periphery and not covered by the gasket. *See, e.g.,* Specification at p. 2, ll. 11-16; p. 3, ll. 1-6; p. 16, ll. 6-23; and Figures 5-6
- Claim 9 relates a facemask having a periphery adapted to abut a user's face and a compressible gasket formed of a breathable filtering material on said periphery of the facemask. The breathable filtering material includes an electret and contains an active agent. The breathable filtering material sits between the periphery of the facemask and a face of a user filling any space that may exist there between. The breathable filtering material provides an air path there through. *See, e.g.,* Specification at p. 2, ll. 11-16; p. 3, ll. 1-6; p. 7 l. 16 – p. 9, l. 6; p. 13, l. 20 – p. 14, l. 7; p. 16, ll. 6-23; and Figures 5-6

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The grounds for rejection to be reviewed on appeal are as follows:

- Claims 1 and 9 are rejected as being unpatentable under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,951,664 to Niemeyer. The Examiner alleges that Niemeyer discloses a combination comprising a permeable facemask having a periphery adapted to abut a user's face, a compressible gasket formed of a permeable filtering material on said periphery and a filtering area filling any space that may exist there between.
- Claims 2-8, 11-16, and 18-25 are rejected as being unpatentable under 35 U.S.C. 103(a) as being obvious over by U.S. Patent No. 4,951,664 to Niemeyer in view of U.S. Patent No. 5,582,865 to Rezuze et al. The Examiner alleges that Niemeyer discloses a combination comprising a permeable facemask having a periphery adapted to abut a user's face, a compressible gasket formed of a permeable filtering material on said periphery and a filtering area filling any space that may exist there between. The Examiner further contends that while Niemeyer does not teach incorporating an active agent in the gasket, it was known in the art to add an active agent to a compressible gasket, as allegedly taught by Rezuze.
- Claims 26 and 27 unpatentable under 35 U.S.C. 103(a) as being obvious over U.S. patent No. 4,951,664 to Niemeyer in view of U.S. Patent No. 5,582,865 to Rezuze et al. as applied to claim 25, and further in view of U.S. Patent No. 4,951,692 to Dhanakoti. The Examiner repeats the rejection of claims 2-8, 11-16 and 18-25

and further adds that Dhanakoti teaches applying an electrical charge to a facemask.

ARGUMENT

In the ensuing argument, we address each of the Examiners grouped rejections in turn and argue some of those claims separately as well pursuant to 37 C.F.R.

§41.37(c)(1)(vii). The groups of claims to be argued are as follows.

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,951,664 to Niemeyer.
2. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,951,664 to Niemeyer.
3. Claims 2-8, 11-16, and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,951,664 to Niemeyer in view of U.S. Patent No. 5,582,865 to Rezuke et al.
4. Claims 3-6, 11-14, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,951,664 to Niemeyer in view of U.S. Patent No. 5,582,865 to Rezuke et al.
5. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,951,664 to Niemeyer in view of U.S. Patent No. 5,582,865 as applied to claim 25, and further in view of U.S. Patent No. 4,951,692 to Dhanakoti.

For the reasons set forth below, Appellant respectfully traverses the rejections of claims 1-9, 11-16 and 18-27.

1. **Claims 1 and 9 are not anticipated by U.S. Patent No. 4,951,664 under 35 U.S.C. 102(b)**

A. Claim 1

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,951,664 to Niemeyer. The Examiner alleges that Niemeyer discloses a combination comprising a permeable facemask (10) having a periphery adapted to abut a user's face, a compressible gasket (30) formed of a permeable filtering material on said periphery and a filtering area filling any space that may exist there between. The Examiner also contends that the compressible gasket is breathable and provides an air path therethrough. *See* Office Action dated February 17, 2009 at pages 2-3. Applicant respectfully traverses the Section 102 rejection.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985). Applying the law to the instant facts, the reference relied upon by the Office Action does not disclose, suggest or enable Applicant's invention.

Applicant argues that Niemeyer fails to teach or suggest at least two elements present in claim 1: breathable filtering material and provide an air path therethrough. As will be discussed below, these two features are essential in generating a novel type of facemask that does not rely on forming an airtight seal between the user's face and the

periphery of the mask as with prior art facemasks, including the mask described in Niemeyer.

Before discussing the cited prior art further, it is first necessary to construct the meaning of the terms used in the claim. The Examiner and Applicant disagree with the meaning of the terms ‘breathable’ and ‘air path’. With respect the term ‘breathable’, the Office Action from February 17, 2009 (page 6) contends that “the Examiner is entitled to use the common denotation of the term breathable and further the term breathable within the context of fabrics wherein the term refers to the ability of a fabric or clothing to transmit air and/or moisture.” Applicant, in turn, has consistently argued that the term ‘breathable’ has a well defined meaning in the facemask arts which is completely consistent with how the term is used in the specification as originally filed. However, the Examiner states that the term ‘breathable’ is not clearly defined in the specification and hence, the definition as applied in the context of fabrics is prevailing.

The Examiner’s reliance on a dictionary definition of the term ‘breathable’ as used in the fabrics industry is not consistent with Federal Circuit case law. It is well established that “the ordinary and customary meaning of a claim term is the meaning the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, *415 F.3d 1303, 1313<, 75 USPQ2d 1321>, 1326< (Fed. Cir. 2005) (*en banc*). *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)(“In the absence of an express intent to impart a

novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.").

Moreover, ordinary meaning refers to **how the term is used in the field of invention**; *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)("[W]ords in patent claims are given their ordinary **meaning in the usage of the field of the invention**, unless the text of the patent makes clear that a word was used with a special meaning.") (emphasis added). Additionally, "it is the person of ordinary skill in the art in the field of invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents **with an understanding of their meaning in the field**, and have knowledge of any special meaning and usage in the field." *Id.* (emphasis added). As will be discussed below, Applicant uses the word 'breathable' consistent with its usage in the facemask literature and not with a special meaning. As such, Applicant disagrees fully with the Examiner's position that Applicant is acting as his own lexicographer in defining the term 'breathable'.

The facemask literature, which dates back over a century, is replete with definitions of the terms 'breathable' and 'breathability'. In fact, the terminology is so common that it is used by manufacturers of masks in product specifications. For instance, the Appendix includes a copy of product specifications for facemasks sold by 3M Company. In this document the properties of facemasks are shown. One property shown is 'Breathability'. There is a footnote 3 which defines breathability and provides a Military Specification therefore. The footnote reads:

³ **Breathability, Delta P (ΔP)**

The pressure drop across a facemask, expressed in mm water/cm². *The higher the Delta P, the more difficult the mask is to breathe through.*

The Method 1 Military Specifications, MIL-M- 36945C 4.4.1.1.1
The specimen mask materials are placed in a special test fixture that measures the pressure on both the inlet and exit sides of the mask during a forced flow of air through the mask. The differential pressure drop across the mask is then measured.

Furthermore, the Appendix includes a product specification from SPERIAN for facemasks which defines breathability as follows:

Measures the difference of air pressure of the inside of the mask and outside of the mask; measures the *pressure drop* across the facemask and is expressed in mm air/cm². *It is an indication of the effort required to breath through the mask.*

Hence, the above definitions clearly indicate that the ordinary meaning of the term breathable in the usage of the field of invention (facemasks) is an indication of the effort required to breath through the mask and is quantitatively determined by measuring pressure drop. The Examiner has argued that the term ‘breathability’ is not found nor addressed in the present specification. *See* advisory action mailed March 30, 2009. The Examiner has also argued that the definitions of breathability given above (e.g., Appendix A), “was not in fact supported within the specification.” *See* interview summary mailed July 29, 2009. However, because the term breathability is used in the specification entirely consistent with the meaning as understood in the facemask art, there is no requirement to define the term in the specification. Even with that being said, it is evident from reading the specification that Applicant is using the term ‘breathable’ as a

measure of air resistance and pressure drop, consistent with the definitions provided above and thus, consistent with how the term is normally applied in the facemask art.

Turning to the specification, there exists ample indication that Applicant is using the term *breathable* consistent with the ordinary meaning of the term in the facemask arts. In The BACKGROUND OF INVENTION section, Applicant points out that the art has focused an airtight seal between the mask and the periphery of the face so that air cannot penetrate through the sides of the mask. However, the pressure differential generated creates gaps between the skin and the periphery of the mask where air can enter, unfiltered. The present invention is directed to solving this significant problem.

Accordingly, Applicant summarizes the invention as follows:

The electrostatic filter of the present invention may be made of a spongy or other *breathable* nonwoven material so as to *minimize the pressure differential*, thus preventing air from being forced through the gaps. Further, it effectively makes the *gasket* used to create a closure between the user and the facemask out of a thin filter having a *low-pressure drop*.....

See Specification at p. 2, ll. 11-15. Additionally, in the DETAILED DESCRIPTION OF THE INVENTION section, Applicant states the following:

According to the present invention there is provided a closure material made of substrate having electrostatic properties and an electrostatic material with an active agent incorporated therein, where the material is a high loft (in one embodiment, approximately, 1" thick) *breathable* material of a tri-dimensional structure and is placed around the mask or air filter in order to not create a so-called airtight junction but instead creates a *breathable* closure that actually covers all the contours of the different geometrical surface to provided a *permeable closure*, having filtering properties. This approach makes the closure into a filter whereby air that bypasses the mask through gaps caused by a non-perfect fit, still passes through the closure and is filtered. In addition, contrary to a

"resilient" closure the pressure differential that is detrimental in an airtight approach is reversed in our approach since *the air following the path of least resistance will pass through the filter material of the mask instead.*

See Specification at p. 16, ll. 6-18

Both passages from the specification clearly show that the term 'breathable' is being used consistently with how it is traditionally applied in the facemask art. Hence, a breathable gasket has a low pressure drop and thus allows air to freely pass through (*i.e.*, low air-resistance). This is wholly different than prior art methods where a seal between the face and the mask is created, resulting in a high pressure drop of the closure that is resistant to air flow.

Turning now to Niemeyer, the Examiner has maintained that the reference teaches a breathable gasket that provides an air path therethrough. However, the references actually teach the exact opposite. The gasket is not breathable and is impermeable to air. In the SUMMARY OF INVENTION section, Niemeyer defines the facemask as having a filtering mechanism, a conforming mechanism and a sealing mechanism. The conforming mechanism is attached to the periphery of the filtering mechanism (facemask) and is designed to abut a person's face. However, unlike the facemask of the present invention, the conforming mechanism is not designed to filter air but rather to avoid air passing through. To ensure impermeability to air, Niemeyer adds a sealing mechanism to the inner portion of the conforming mechanism. See Niemeyer at Column 2, ll. 30-42. In defining the sealing mechanism, Niemeyer states the following:

A third material, comprising the sealing mechanism, is attached to the side of the foam strip opposite the side attached to the filter material and extends for attachment to the filter material. In this way, *the impenetrable material* is

in contact with the person's face, and ***provides a seal*** between the face and the filter material.

Id. at Col. 2, ll. 47-53 (emphasis added). Niemeyer goes on to state the following:

The method of manufacture of the present mask ensures ***impermeability of air*** during a breathing cycle across the conforming mechanism and the sealing mechanism.

Id. at Col. 3, ll. 23-26 (emphasis added). Claim 1 of Niemeyer also indicates that the sealing mechanism (third material) is impermeable to air.

Accordingly, Niemeyer discloses a gasket that forms a seal with the face of a user and is this impermeable to air. Niemeyer notes that the third material (32) “always maintains a seal.” *Id.* at col. 6, ll. 25-26. Moreover, Niemeyer states that “third material (32) maintains a seal thereby requiring breathable air to pass through the filtering layer (16). *Id.* at col. 5, ll. 46-31. (emphasis added). Hence, it is clear that Niemeyer intends to form an airtight seal between the periphery of the mask and the user’s face, which is exactly what is described in the BACKGROUND section of the present specification in regards to prior art facemasks.

As stated above, the presently claimed facemask does not intend to form such a seal but rather allow air to pass through and be filtered. The present invention achieves this by creating a low pressure drop between the outside of the filter and the inside of the filter (*i.e.*, generating a breathable gasket). The conforming method of Niemeyer on the other hand, would have a very large pressure drop owing to the presence of the sealing mechanism. Thus, the conforming method would not be breathable in accordance with the definition in the facemask art (*see* discussion above). Moreover, the conforming mechanism would not create an air path therethrough being that the sealing mechanism is

purposefully designed to block air from flowing through. Hence, the mask described in Niemeyer and the mask of the present invention, as defined in claim 1, act in a completely different manner.

The Examiner has argued that Niemeyer discloses that third material (32) is impermeable to particles as small as 5 micron (Col .5, ll. 9-10). Based on this disclosure, the Examiner alleges that air can pass through the third material (32) thus creating a breathable gasket. Again, the Examiner is not taking into account the ordinary definition of the term breathable as used in the facemask art. As discussed at length at above, ‘breathable’ relates to pressure drop and air resistance. The fact that Niemeyer is creating a seal between the mask and the user’s face precludes breathability. A seal is designed to resist air flow through by generating a high pressure drop. This is made clear in the specification of Niemeyer which states that the “method of manufacture ensures impermeability of air” of third material (32) and “requires breathable air to pass through the filtering layer (16)”. *See Id.* at Col. 3. ll. 23-26 and Col. 5. ll. 50-51. Even if, as the Examiner alleges, a small amount of air can pass through the third material, this by no means implies that the material is breathable. The Examiner is defining the term ‘breathable’ so broadly that it would fail to take on any significant meaning.

It is further noted that in the same paragraph that the Examiner cites regarding the third material (32) being impermeable to air as small as 5 microns, Niemeyer indicates that an acceptable third material (32) is the rubber used in condoms. The rubber used in condoms cannot be considered ‘breathable’ as asserted by the Examiner.

With respect to the limitation “providing an air path therethrough”, the Examiner argues that gasket (30) allows air to be forced out of or adsorbed during compression or

expansion. (Col 2, Lines 53-56). However, the language in Niemeyer clearly indicates that air can go in through one side only and thus, no air path is created. In the present invention, air passes through the gasket and is filtered. In Niemeyer, impermeable material (32) prevents the gasket from providing such as air path. Niemeyer states that impermeable material (32) “always forms a seal.” Col. 6, l. 26. This ensures “impermeability of air during a breathing cycle across the conforming mechanism and the sealing mechanism.” Col. 3, ll. 23-26. Clearly, then there is no air path through the conforming mechanism but rather, air flow is blocked. In fact, if such an air path existed, this would be contrary to Niemeyer’s proposed invention where air passes through filtering layer (16). Instead, as the Examiner indicated, the air that enters conforming mechanism (30) is used for compression and expansion of the conforming mechanism.

For at least thee reasons, Applicant requests that the rejection of claim 1 over 35 U.S.C. 102(b) be withdrawn.

B. Claim 9

Claims 9 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,951,664 to Niemeyer. The Examiner provides the same reason for rejecting claim 9 as was provided by claim 1. However, the Examiner does not comment on the added limitation in claim 9: an active agent incorporated therein on said periphery. In fact, on page 3 the Office Action dated February 17, 2009 the Examiner states that Niemeyer “does not expressly disclose the incorporation of active agents within the compressible gasket.”

Additionally, the Examiner does not comment on the added limitation in claim 9: gasket includes an electrostatic charge there across. Applicant argues that Niemeyer does

not disclose incorporating an electrostatic charge in either conforming mechanism (30) or the impermeable material (32).

Thus for at least these reasons and at least the reason expressed with respect to claim 1, Applicant requests that the rejection of claim 9 over 35 U.S.C. 102(b) be withdrawn.

2. Claims 2-8, 11-16, and 18-25 are not obvious under 35 U.S.C. 103(a) over U.S. Patent No. 4,951,664 in view of U.S. Patent No. 5,582,865

A. Claims 2, 7-8, 15-16, and 21-25

Claims 2, 7-8, 15-16 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,951,664 to Niemeyer in view of U.S. Patent No. 5,582,865 to Rezuke et al. The Examiner alleges that Niemeyer discloses a permeable facemask but does not expressly disclose incorporation of an active agent. The Examiner further alleges that it was well-known to incorporate active agents into compressible gaskets, as exemplified by Rezuke. *See* Office Action from February 17, 2009 at page 3. Applicant respectfully traverses the Section 103 rejection.

Claims 2, 7-8, 15-16, 21-25 each are generally directed to a combination comprising a facemask and a breathable gasket containing an active agent. Niemeyer, which was discussed at length in the previous section, does not teach a breathable gasket containing an active agent. The Examiner contends that Niemeyer teaches a permeable facemask. While this may be true, the permeable portion of the Niemeyer facemask is the filtering layer (16), not the gasket. Hence, the Examiner's remarks concerning the permeability of the Niemeyer facemask are not relevant to the pending claims.

Presumably, the Examiner is arguing that it would be obvious to put an active agent into the conforming mechanism (30) of the Niemeyer facemask, thus creating a

biocidal gasket material. However, this line of reasoning suggests that the Examiner is reaching the erroneous conclusion that conforming mechanism (30) is intended to be used as a filter, as in the present claims. Clearly, this is not the case. As discussed above, the conforming mechanism (30) which its attached impermeable seal (32) is designed to form an airtight seal, thus rendering it impermeable to air. As such, Niemeyer does not contemplate the conforming mechanism (30) as a filtering mechanism, as with the presently claimed breathable gasket. As such, placing an active agent into the conforming mechanism (30) would be counterintuitive. The active agent would serve no purpose in the mask described by Niemeyer. Moreover, it is possible that placing such an active agent into the conforming mechanism (30) would disrupt the association between the conforming mechanism (30) and the sealing mechanism (32), this hindering the desired intention of the mask.

The Examiner is also erroneous in asserting that Rezuke discloses a compressible gasket with an active agent. Rezuke discloses a nonwoven composite material comprising a nonwoven carrier impregnated with chemical absorbent. Rezuke further teaches that the composite material (16) can be molded into a face mask. *See* Rezuke at Col. 3, ll. 5-9. A gasket is defined as an object that fills the space between two other objects when under compression. Rezuke does not disclose or suggest that that the composite material (16) can be molded into a gasket, particularly a gasket adapted to be placed around the periphery of a facemask.

Thus, both Niemeyer and Rezuke would not solve the problems alluded to in the present application. Unlike Niemeyer and Rezuke, Applicant has determined that by allowing air to pass through the gasket on the periphery of a mask rather than creating an

airtight sea, problems of having unfiltered air passing through gaps in the facemask can be substantially or wholly avoided. Applicant has thereby developed a new method of using a protective facemask by using a gasket on the periphery of the mask as a primary filtering element. The addition of an active agent ensures high antibiocidal efficiency of air passing through the breathable gasket.

As there appears to be no basis for combining Niemeyer and Rezuze as the Examiner suggests, the Examiner appears to be using hindsight based solely on the present specification. Applicants remind the Examiner that it is impermissible to engage in a hindsight reconstruction of the claimed invention, using the Applicant's structure as a template, and selecting elements from references to fill in the gaps. *Interconnect Planning*, 744 F.2d 1132, 1143 (Fed. Cir. 1985).

For at least these reasons, Applicant requests that the rejection of claims 2, 7-8, 15-16 and 21-25 over 35 U.S.C. 103 be withdrawn.

B. Claims 3-6, 11-14, and 18-20

Claims 3-6, 11-14, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,951,664 to Niemeyer in view of U.S. Patent No. 5,582,865 to Rezuze et al. The Examiner alleges that Niemeyer discloses a permeable facemask but does not expressly disclose incorporation of an active agent. The Examiner further alleges that it was well-known to incorporate active agents into compressible gaskets, as exemplified by Rezuze. *See* Office Action from February 17, 2009 at page 3. Applicant respectfully traverses the Section 103 rejection.

Claims 3-6, 11-14, and 18-20 each are generally directed to a combination comprising a facemask and a breathable gasket which is a porous dielectric carrier. Niemeyer, which was discussed at length in the previous section, does not teach a

breathable gasket that provides an air path therethrough. Also for reasons discussed with respect to the rejections over claims 2, 7-8, 15-16, and 21-25, Rezuke does not teach a compressible gasket material. Combining the two references does not arrive at the presently claimed invention. In addition, the Examiner provides no motivation or other relevant basis for combining the references as such.

For at least these reasons, Applicant requests that the rejection of claims 3-6, 11-14, and 18-20 over 35 U.S.C. 103 be withdrawn.

3. Claims 26-27 are not obvious under 35 U.S.C. 103(a) over U.S. Patent No. 4,951,664 in view of U.S. Patent No. 5,582,865, and in further view of U.S. Patent No. 4,951,692

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,951,664 to Niemeyer in view of U.S. Patent No. 5,582,865 to Rezuke et al., and in further view of U.S. Patent No. 4,951,692 to Dhanakoti. The Examiner alleges that Niemeyer discloses a permeable facemask but does not expressly disclose incorporation of an active agent. The Examiner further alleges that it was well-known to incorporate active agents into compressible gaskets, as exemplified by Rezuke. *See* Office Action from February 17, 2009 at page 3. The Examiner additionally alleges that Dhanakoti teaches the use of a layered electrostatic charge across a facemask. Hence, the Examiner contends that it would be obvious to combine the three references to arrive at the invention claimed in claims 26-27 of the present invention. Applicant respectfully traverses the Section 103 rejection.

For reasons already discussed in Section II, the Examiner has not provided a reasonable basis for combining Niemeyer and Rezuke without the use of improper

hindsight. The same holds true for incorporating an electret into the breather gasket situated on the periphery of the inventive facemask. The purpose of adding an electret, to a facemask, as described in Dhanakoti , is to reduce the pressure drop and increase filtering efficiency of the facemask. Due to the fact that Niemeyer is using the conforming mechanism (30) with its attached impermeable seal (32) as an airtight seal, decreasing pressure drop by adding an electret to the conforming mechanism (30) would work against the intended purpose of the conforming mechanism (30) disclosed in Niemeyer.

In the present invention, incorporating the electret in the breathable gasket when used in combination with an active agent confers outstanding filtration efficiency to the gasket. This increased filtration effectiveness was noted by the Examiner in the Interview Summary from the Examiner dated July 22, 2009.

For at least these reasons, Applicant requests that the rejection of claims 26-27 over 35 U.S.C. 103 be withdrawn.

CONCLUSION

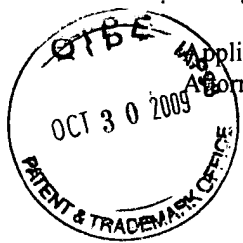
In view of the arguments above, Appellants respectfully submit that claims 1-9, 11-16 and 18-27 are patentable and urge the Board of Patent Appeals and Interferences to reverse all of the Examiner's rejections as to each of these claims.

To the extent any extension of time under § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account No. 06-0923.

Respectfully submitted,

Date: October 27, 2009

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CLAIM APPENDIX TO APPEAL BRIEF UNDER RULE
41.37(c)(1)(viii)

1. (Previously presented) A combination comprising:

a facemask having a periphery adapted to abut a user 's face; and a compressible gasket formed of a breathable filtering material on said periphery of said facemask adapted to provide an air path there through and to sit between said periphery of said facemask and a face of a user thereby filling any space that may exist there between: said facemask having an area for filtering air which is interior to said periphery and not covered by said gasket.
2. (Previously presented) The combination as in claim 1 wherein said compressible gasket includes an active agent incorporated therein.
3. (Previously presented) The combination as in claim 1 wherein said compressible gasket comprises a porous dielectric carrier.
4. (Previously presented) The combination as in claim 3 wherein said porous dielectric carrier is a non-woven material.
5. (Previously presented) The combination as in claim 3 wherein said porous dielectric carrier is a fiber based material having a fibrous three dimensional matrix structure.

6. (Previously presented) The combination as in claim 3 wherein said porous dielectric carrier is a sponge like material have an open cell matrix structure.
7. (Previously Presented) The combination as in claim 2 wherein said active agent is selected from the group consisting of metals and chemical compounds.
8. (Previously presented) The combination as in claim 2 wherein said active agent is an iodinated resin.
9. (Previously presented) A combination comprising:
a facemask having a periphery adapted to abut a user's face; and
a compressible gasket formed of a breathable filtering material having an active agent incorporated therein on said periphery of said facemask adapted to provide an air path there through and to sit between said periphery of said facemask and a face of a user thereby filling any space that may exist there between; said facemask having an area for filtering air which is interior to said periphery and not covered by said gasket; wherein said compressible gasket includes an electrostatic charge there across.
10. (Cancelled)
11. (Previously presented) The combination as in claim 9 wherein said compressible gasket comprises a porous dielectric carrier.

12. (Previously presented) The combination as in claim 11 wherein said porous dielectric carrier is a non-woven material.
13. (Previously presented) The combination as in claim 11 wherein said porous dielectric carrier is a fiber based material having a fibrous matrix structure.
14. (Previously presented) The combination as in claim 11 wherein said porous dielectric carrier is a sponge like material have an open cell matrix structure.
15. (Previously presented) The combination as in claim 9 wherein said active agent is selected from the group consisting of metals and chemical compounds.
16. (Previously presented) The combination as in claim 9 wherein said active agent is an iodinated resin.
17. (Cancelled)
18. (Previously presented) The combination as in claim 5 wherein said fiber matrix structure is configured to entrap the active agent in said three dimensional matrix structure.
19. (Previously presented) The combination as in claim 5 wherein the active agent is intermeshed with the fiber based material.

20. (Previously presented) The combination as in claim 4 wherein said nonwoven material comprises a polymer fiber selected from the group consisting of nylon, polyethylene and polypropylene.
21. (Previously presented) The combination as in claim 2 wherein said active agent is a biostatic and/or biocidal material.
22. (Previously presented) The combination as in claim 2 wherein the active agent is selected from the group consisting of silver, copper, halogenated resin, and activated carbon.
23. (Previously presented) The combination as in claim 2 wherein the active agent is a metal, said metal selected from the group consisting of aluminum, barium, boron, calcium, chromium, copper, iron, magnesium, manganese, molybdenum, nickel, lead, potassium, silicon, sodium, strontium and zinc.
24. (Previously presented) The combination as in claim 2, wherein the active agent is a chemical compound selected from the group consisting of N-methyl piperazine, potassium hydroxide, zinc chloride, calcium chloride and a mixture of sodium carbonate and sodium bicarbonate.

25. (Previously presented) The combination of claim 18 wherein the fiber based material includes an electrostatic charge there across, said electrostatic charge capable of generating a potential across the surface of said fiber based material.

26. (Previously presented) The combination of claim 25 wherein the electrostatic charge is single or multi-layered.

27. (Previously presented) The combination of claim 26 wherein the electrostatic charge is about 25 Kv.

28-29. (Canceled)

EVIDENCE APPENDIX TO APPEAL BRIEF UNDER RULE
41.37(c)(1)(ix)

- 3M Infection Prevention Solutions: Face Masks and Respirators (Product Specifications)
- Sperion Respiratory Protection: ONE-Fit® Healthcare Respirators (Product Specifications)

RELATED PROCEEDINGS APPENDIX TO APPEAL BRIEF
UNDER RULE 41.37(c)(1)(x)

There are no related proceeding decisions being cited.

Product Name	Catalog Number	Filtration BFE ¹	Breathability ² (ΔP, mm H ₂ O/cm ²)	Anti-Fog Feature	Face Shield Availability
3M™ Aseptic™ Molded Surgical Mask	1800+NL	>96%	<2.0	n/a	—
3M™ Tie-on Surgical Mask	1818	>99%	<2.0	n/a	1818 FS
3M™ Anti-Fog Surgical Mask with Foam	1818FS	>99%	<2.0	Yes	—
3M™ Anti-Fog Surgical Mask with Foam	1832	>99%	<2.3	Foam strip	—
3M™ High Fluid-Resistant Tie-on Surgical Mask	1835	>99%	<2.8	n/a	1835FS
3M™ Filtron™ High-Performance Tie-on Surgical Mask	1838	>99%	<2.0	Duckbill style	—
3M™ Standard Procedure Mask	1826	>95%	<2.0	n/a	—
3M™ High Fluid-Resistant Procedure Mask	1840	>99%	<2.8	n/a	1840FS
3M™ N95™ Health Care Particulate Respirator and Surgical Mask -cone	1860	>99%	<6.5	Foam strip	—
3M™ N95™ Health Care Particulate Respirator and Surgical Mask -three-panel, flat-fold	1870	>99%	4.9	Foam strip	—

1. BFE % (Bacterial Filtration Efficiency)

In Vitro: ASTM F2101-01
A standard procedure for comparison of filtration materials. It measures the percent efficiency at which the facemask material restricts bacteria from passing through the mask. This test evaluates how well a respirator or surgical mask can prevent biological particles from being expelled by the wearer into the environment. The mask material is subjected to an aerosol of *Serratia marcescens* bacteria at a constant flow rate. Bacterial particles generated during the BFE test are "large" on the order of 1 to 5 microns in size with a mean diameter of 3 microns. A particle size sampler with agar plates measures bacteria with and without the mask material in place, and a percent efficiency is calculated.

In Vivo: Modified Greene and Vesley Method

A standard procedure for measuring the percent efficiency at which the facemask restricts bacteria from passing through the mask while wearing it on the face. A mask is placed on a person, and the concentration of exhaled bacterial particles with a mean diameter of 4 to 5 microns is measured both with and without the mask present. The test chamber, along with an Anderson sampler, captures microorganisms that escape and the percent efficiency is calculated.

Note: particle used for Respirator Filtration Efficiency tests are much smaller, approximately 0.3 microns in size. The BFE test is a relative indicator of the performance of a medical, surgical or patient care mask but the results cannot be compared to Respirator Certification Filtration Efficiency.

2. PFE % (Particulate Filtration Efficiency)

This In Vitro Particulate Challenge: Test ASTM F2299-03 (ASTM F 1215-99) is a standard test method that measures the percent efficiency at which the facemask restricts particulate matter from passing through the mask. It measures the filter efficiency of a surgical or patient care mask against an aerosol created from a solution of water and latex spheres with a mean diameter of 0.1-micron particles at a flow rate of less than 30 liters per minute (LPM). Particle counts of the upstream and downstream flows are measured with a laser particle counter. This testing provides an evaluation of Submicron Efficiency Performance, when the material is greater than or equal to 99%.

Note: Particulate Respirator Filters are tested against particles of approximately 0.3 microns in size at 85 LPM. Because the test conditions are not the same, the filter efficiency results of these two types of testing cannot be compared.

3. Breathability: Delta P (ΔP)

The pressure drop across a facemask, expressed in mm water/inch. The higher the Delta P, the more difficult the mask is to breathe through.

The Method 1 Military Specifications, MIL-M-36945C 4.4.1.1.1 The specimen mask materials are placed in a special test fixture that measures the pressure on both the inlet and exit sides of the mask during a forced flow of air through the mask. The differential pressure drop across the mask is then measured.

Note: the MIL-M-36945C 4.4.1.1.1 testing method differs from other breathability testing methods. These values are on different scales and parameters and cannot be compared.

Fluid Resistance

The ability of a facemask's material construction to minimize fluids from traveling through the material and potentially coming in contact with the user of the facemask. Fluid resistance helps reduce potential exposure to blood and bodily fluids caused from splashes, sprays or spatters.

ASTM F 1862-06a is a standard test method for resistance of medical facemasks to penetrate synthetic blood. An actual mask is conditioned in a high humidity environment to simulate human use and is placed on a test holder. Synthetic blood (2cc) is shot horizontally at the mask at a distance of 30 cm (12 inches). Surgical masks are tested on a pass/fail basis at three velocities corresponding to the range of human blood pressure (80, 120, 160 mmHg). The inside of the mask is then inspected to see if any synthetic blood has penetrated to the inside of the mask. Fluid resistance according to this testing method is when the device passes at any level.

References

1. FDA Guidance for Industry and FDA Staff, Surgical Masks, www.fda.gov/oc/ohrt/surgicalmasks.pdf
2. NIOSH, The United States National Institute for Occupational Safety and Health, www.niosh.gov
3. NIOSH, The United States National Institute for Occupational Safety and Health, www.niosh.gov
4. Modified Greene and Vesley, Surgical Laboratory, Inc., 2001, Lake City, UT.
5. Later Panel Challenge test method, Robert Laboratories, Inc., 2001, Lake City, UT.

***N95 Respirator NIOSH Certified Filter Efficiency**
NIOSH particulate respirator approval requirements under 42 CFR 84: All particulate respirator filters are tested against 0.3-micron aerodynamic diameter particles (the most penetrating particle size) at 85 liters/minute. Therefore an N95 has a particulate filtering efficiency of 95% of the most difficult particle size (0.3-micron).

Attachment Design	Style	Additional Features
Single elastic band	Cone-molded	Latex free
Tie-on (Horizontal)	Bi-directional pleats	Our most popular, Soft, High comfort
Tie-on	Bi-directional pleats	Our premium anti-fog, anti-reflective face shield
Tie-on	Bi-directional pleats	Closed-cell, medical grade foam anti-fog strip
Tie-on	Bi-directional pleats	Superior fluid resistance and breathability
Tie-on	Bi-directional pleats	Anti-fog face shield, Black anti-glare strip
Tie-on	Duckbill style	Fog-free design, Off-the-face comfort
Earloop	Standard pleats	Economical, Convenient earloop attachment
Earloop	Bi-directional pleats	Superior fluid resistance, OR compatible
Earloop	Bi-directional pleats	Anti-fog face shield, Black anti-glare strip
Double	Cone-molded elastic band	Standard size surgical/laser mask
Double elastic band	Cone-molded	Small size
Double elastic band	Flat fold, three-panel	Soft inner liner, Individually packaged surgical/laser mask, Single dispensing

For more information contact your 3M Infection Prevention Solutions representative or call 1 800 3M Helps. You can also visit us online at www.3M.com/CA/IP.



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3M Infection Prevention Solutions

Face Masks and Respirators

A full line for your infection prevention and personal protection needs from a healthcare leader.



*Proven performance.
Breathable comfort.*



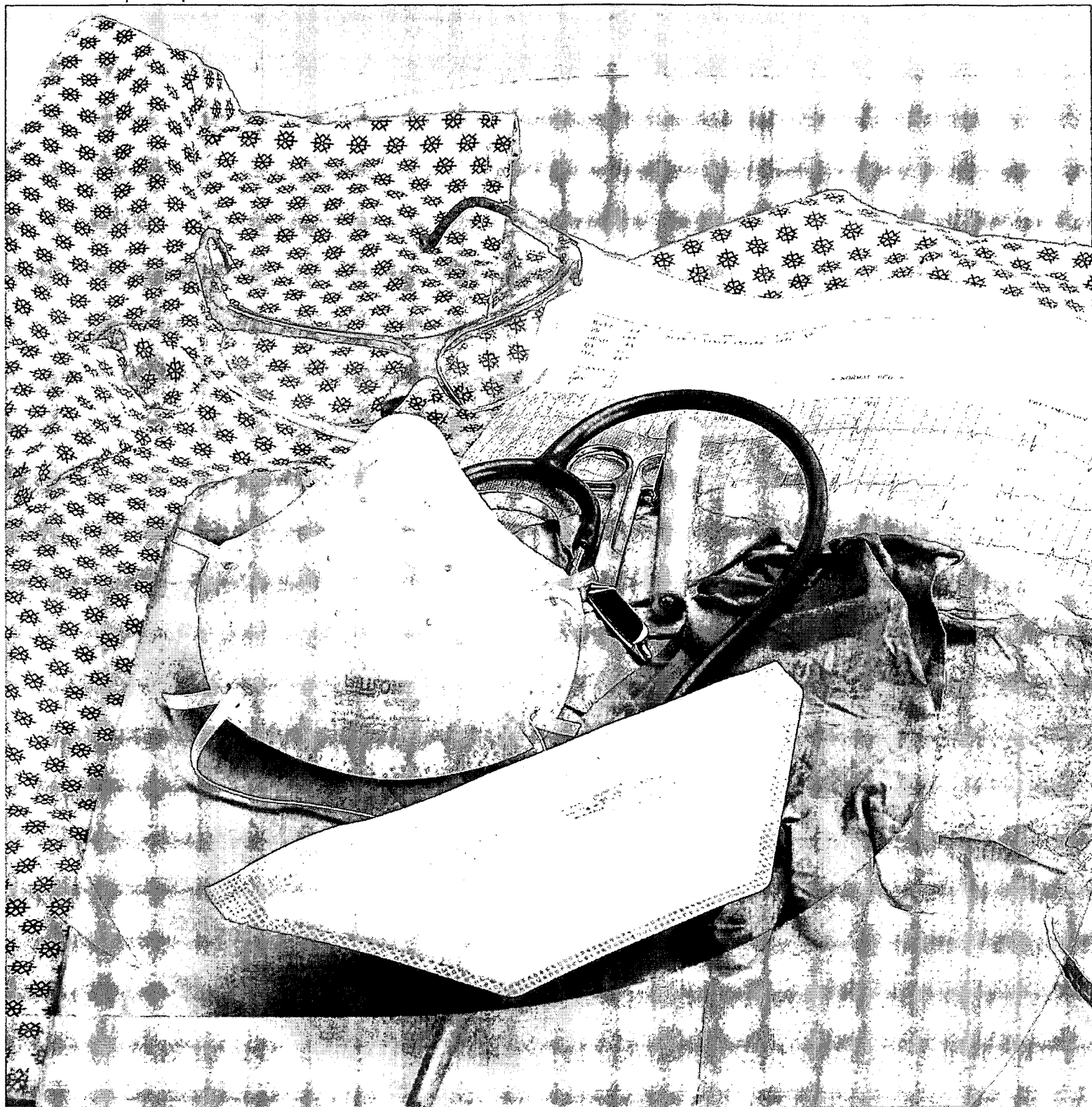
Surgical & Specialty Masks



Procedure Masks



N95 Healthcare Respirators



>>> RESPIRATORY PROTECTION

ONE-Fit® HEALTHCARE RESPIRATORS

SPERIAN
Protection you can trust

ONE-Fit® Flat Fold and Cup Style Respirators for Healthcare Use



N95

DISPOSABLE PARTICULATE RESPIRATOR AND SURGICAL MASK

For over 100 years, Sperian® has provided respiratory protection around the world. The Sperian brand of disposable respirators offers a comprehensive arsenal of disposable respirators.

For years, disposable respirators have been constructed with a variety of polyester fibers. The ONE-Fit™ Healthcare respirators are constructed with electrostatic, non-woven; melt blown polypropylene filtering media, fiber that ensures 95% filtration efficiency against non-oil airborne particles.

While there have been advances with disposable respirators, the ONE-Fit Healthcare N95 molded cup and flat fold respirators utilize advanced technology in their proprietary filtering media to create an improved crush resistance shell for the molded cup style respirator, and a light weight thin film layer in the flat fold version. These features make the ONE-Fit Healthcare products an excellent choice for hospitals, government, pandemic preparedness, and civilians use.

HC-NB295F ONE-Fit Flat Fold

Latex-Free Construction

Elastic Head Straps are Sonic Welded to Inside of Outer Layers

Thin Light-Weight Construction

Soft Inner Layer Designed for Comfort and Convenience

The ONE-Fit Healthcare HC-NB095 and HC-NB295F particulate respirator and surgical masks are NIOSH-approved as N95 respirators and listed with the FDA as a medical device. They are designed for the healthcare setting and for use in the emergency room, operating room, intensive care unit, and meet CDC guidelines for M. tuberculosis. Engineered as one universal size, the HC-NB095 and the HC-NB295F offer secure protection and comfortably fit a variety of face sizes and shapes.

HC-NB095 ONE-Fit Molded Cup

Light-Weight and Rigid Outer Shell that Resists Collapsing

Contours the Natural Shape of the Face

Inner Layer Ultrasonically Welded to Outer Shell in the Front at 6 Points

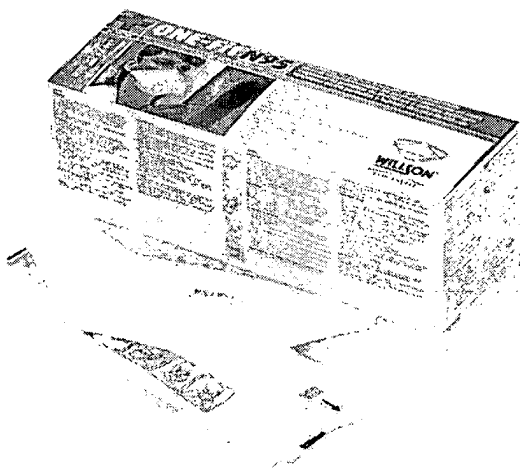
Latex-Free Construction

Soft Inner Layer Designed for Comfort and Convenience

The ONE-Fit Healthcare N95 particulate respirator and surgical masks are light weight and offer the wearer a soft inner lining for increased comfort against the face. With the respirator meeting ASTM standards for fluid and splash resistance, it aids in reducing potential exposure to blood, saliva, and other bodily fluids.

HC-NB29F

ONE-FIT® FLAT FOLD



Features

- Light weight and thin construction, with a soft inner layer designed for comfort and convenience
- Elastic head straps are sonic welded inside the outer layers
- Masks are individually bagged to keep from soiling and contamination
- Tear away section on the bag for easy opening
- Dispenser style box with tear-out/cut-out panel for ease of access
- Latex-free and silicone-free construction

Usages

- N95 particulate respirator
- Surgical mask
- Pandemic preparedness studies recommend as sufficient protection against many substances including diseases such as H5N1 Avian Flu and SARS

Performance

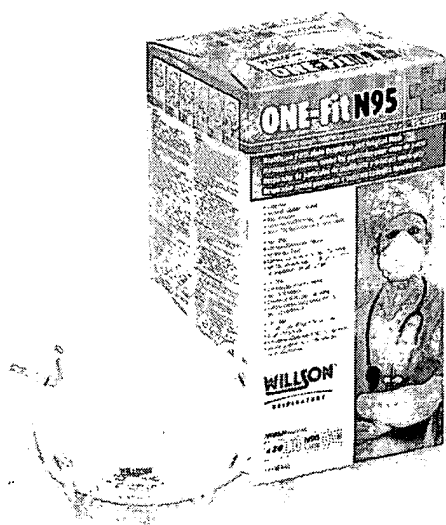
- NIOSH-approved as an N95 particulate respirator for potential respiratory exposure to potentially lethal agents such as Anthrax
- Proprietary technology that makes the mask incredibly light weight (33% less) increasing wear time and decreasing wearer fatigue
- A universal one size respirator, designed to fit most face sizes and shapes
- Meets CDC guidelines for M. tuberculosis exposure control
- Ranks as "high barrier" class 160 mmHg in conformance to ASTM F1862 requirements for fluid penetration and splash resistance
- Provides >99.9% (BFE) Bacterial Filtration Efficiency
- Offers >99.5% (PFE) Particle Filtration Efficiency
- Offers >99.9% (VFE) Viral Filtration Efficiency
- Exceeds NIOSH breathability performance specifications for ΔP
- Reduces the transfer of microorganisms and other airborne particulate matter
- Reduces wearer exposure to airborne particulates smaller than 0.1 micron – appropriate for laser and electrocautery procedures

Ordering Information

Model Number	HC-NB295F
Part Number	14110451
UOM	Box
Description	ONE-Fit Flat Fold N95 Healthcare Particulate Respirator and Surgical Mask
Packaging	20 Masks Per Box, Individually Bagged, Dispenser Style Box with Tear-Away Portion for Access
Box Dimensions	10.9" Wide x 3.9" Deep x 3.9" Tall
Box Weight	0.48 lbs
Case Quantity	10 Boxes Per Case, 200 Masks Total
Case Dimensions	19.5" Wide x 8.3" Deep x 11.7" Tall
Case Weight	5.37 lbs

HC-NB095

ONE-FIT[®] MOLDED CUP



Features

- Light weight and rigid outer shell that resists collapsing, with a soft inner layer designed for comfort and convenience
- Inner layer ultrasonically welded to outer shell in the front at six points to eliminate being drawn into mouth and nose area during inhalation
- The masks are all bagged into a single plastic sleeve to protect from exposure and contamination when the box is opened
- Plastic sleeve bag with a tear away portion for easy opening
- The mask contours with the natural shape of a face minimizing pressure point
- Latex-free and silicone-free construction

Usages

- N95 particulate respirator
- Surgical Mask
- Pandemic preparedness studies recommend as sufficient protection against many substances including diseases such as H5N1 Avian Flu and SARS

Performance

- NIOSH-approved as an N95 particulate respirator for potential respiratory exposure to potentially lethal agents such as Anthrax
- Proprietary technology that makes the mask incredibly light weight (33% less) increasing wear time and decreasing wearer fatigue
- A universal, one size respirator, designed to fit most face sizes and shapes
- Meets CDC guidelines for M. tuberculosis exposure control
- Ranks as "high barrier" class 160 mmHg in conformance to ASTM F1862 requirements for fluid penetration and splash resistance
- Provides >99.9% (BFE) Bacterial Filtration Efficiency
- Offers >99.5% (PFE) Particle Filtration Efficiency
- Offers >99.9% (VFE) Viral Filtration Efficiency
- Exceeds NIOSH breathability performance specifications for ΔP
- Reduces the transfer of microorganisms and other airborne particulate matter
- Reduces wearer exposure to airborne particulates smaller than 0.1 micron – appropriate for laser and electrocautery procedures

Ordering Information

Model Number	HC-NB095
Part Number	14110446
UOM	Box
Description	ONE-Fit Molded Cup N95 Healthcare Particulate Respirator and Surgical Mask
Packaging	20 Masks Per Box, Plastic Sleeve Bag with Tear-Away Portion for Easy Opening
Box Dimensions	5.4" Wide x 5.0" Deep x 9.6" Tall
Box Weight	0.50 lbs
Case Quantity	10 Boxes Per Case, 200 Masks Total
Case Dimensions	25.4" Wide x 11.4" Deep x 10.6" Tall
Case Weight	5.91 lbs

ONE-Fit® HEALTHCARE RESPIRATORS

PROTECTION AND COMFORT

Technical Glossary

N95 Respirator Certification Test

NIOSH required test for N95 respirators that measures filter efficiency and penetration of a 0.3 µm sodium chloride particle aerosolized at a flow rate of 85 liters per minute at 95% filtration efficiency.

ASTM F1862 Fluid Resistance Test

Fluid Resistance is defined as the ability of a facemask's material construction to minimize fluid traveling through the material and potentially coming into contact with the user of the facemask. The test simulates the fluid splash resistance of a facemask under conditions similar to actual use. The masks are evaluated at three pressures, 80, 120, and 160. The higher the pressure at which a mask passes, the greater the fluid splash resistance.

Particulate Filtration Efficiency (PFE)

Measures the percent efficiency at which a facemask respirator filters particulate matter passing through; particles range in size from 0.1 to one micron/micrometer, µm.

Bacterial Filtration Efficiency (BFE)

Measures the filtration efficiency by percent using viable (live) bacterial cells that vary in size from one to five microns (micrometer, µm).

Viral Filtration Efficiency (VFE)

Measures the filtration efficiency by percent using the phiX174 bacteriophage as a challenge organism, which is one of the smallest known viruses at 27 nm (0.027µ) in size, has no envelope, and has icosahedral morphology.

Breathability/Differential Pressure (ΔP) 'Delta P'

Measures the difference of air pressure of the inside of the mask and the outside of the mask; measures the pressure drop across the facemask and is expressed in mm air/cm². It is an indication of the effort required to breath through the mask.

Respiratory Protection Standards

Use of respirators in the workplace is regulated by OSHA Respiratory Protection Standards 29 CFR 1910.134. This requires an appropriate respirator program be established, which includes a written program, employee training, respirator fit testing, medical monitoring and program documentation and maintenance. OSHA requires that all respirators be properly fit tested using a quantitative or qualitative fit test when initially assigned to a user, and periodically thereafter. Respiratory protection standards are available from your Sperian respiratory representative.

Respiratory Training Program

Sperian Protection offers a complete respirator training program to assist your facility in achieving compliance with OSHA regulations. Materials include:

- OSHA MedCert online medical evaluations
- Sample respirator programs and training materials
- Respirator use and maintenance program and training materials
- Various respirator fit test kits and training materials

For More Information

For more information on Sperian® disposable respirator products or for ordering information, contact your local Sperian Protection sales representative or call Sperian Protection respiratory customer care at 800.821.7236.

⚠ WARNING! This document provides only an overview of the respiratory products shown. It does not provide important product warnings and instructions. Sperian recommends all users of respiratory equipment undergo thorough training and that all warnings and instructions provided with the products be thoroughly read and understood prior to use. Failure to read and follow all product warnings and instructions may result in serious personal injury, illness or death.

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APPENDIX

CLAIM APPENDIX TO APPEAL BRIEF UNDER RULE 41.37(c)(1)(viii)

EVIDENCE APPENDIX TO APPEAL BRIEF UNDER RILE 1.37(c)(1)(ix)

RELATED PROCEEDINGS APPENDIX TO APPEAL BRIEF UNDER
RULE 41.37(c)(1)(x)